IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
This document relates to: **Ethicon Wave 1 cases listed in Exhibit A**	

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE OR OTHERWISE LIMIT THE OPINIONS AND TESTIMONY OF SCOTT SERELS, M.D.

INTRODUCTION

Dr. Serels is a urologist from Norwalk, Connecticut, a longtime paid consultant for various mesh manufacturers, including Ethicon, and an "advocate of Ethicon mesh products," who has been hired by Ethicon to prepare a general report on the GYNECARE TVT Retropubic mesh implant ("TVT"). *See* Exhibit B (Deposition of Scott Serels, M.D., 4/7/16), 20:1-3; 21:21-22:3; 8:2-24; 52:22-57:12; *see generally* Exhibit C (Serels Report); Exhibit D (Serels Curriculum Vitae). Dr. Serels spent only "three or four hours" reviewing his reliance materials and authoring his report, which contains all of the opinions he intends to offer in this litigation. Ex. B, 8:11-21; 21:21-22:3; Ex. E (Serels Reliance List).

Dr. Serels's own summary of his opinions is as follows:

- The TVT's design and material is reasonably safe for its intended use;
- The Instructions for Use adequately and appropriately warns physicians trained in the surgical treatment of stress urinary incontinence of the potential adverse reactions associated with the device.

Ex. C, § I.9. More specifically, Dr. Serels concludes that certain "complications occur in all procedures for stress incontinence and are not unique to mid-urethral slings," that "the TVT appears safer than either the Burch procedure or pubovaginal sling," that mesh does not degrade or undergo particle loss, that there is no clinical difference between mechanical and laser-cut mesh, that claims of cytotoxicity "are not accompanied by any methodologically sound or scientific analysis, and is [*sic*] completely lacking in clinical significance," and that roping and curling of the mesh result from too much applied tension, "which is clearly contrary to what is outlined in the surgical steps of the IFU." *Id.* at § III.

As explained below, both Dr. Serels's report and deposition testimony reveal that he is unqualified to offer many of these opinions. Further, even assuming qualifications, these opinions are, at most, *ipse dixit* and should be excluded.

STATEMENT OF LAW

"A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." F.R.E. 702. In the context of Rule 702, "'knowledge' connotes more than subjective belief or unsupported speculation." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993). Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the matters upon which she will opine are clearly within her area of expertise." *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D. N.C. 2007).

If the expert is qualified, "[t]he U.S. Supreme Court [has] established a two-part test to govern the admissibility of [the] expert testimony under Rule 702—the evidence is admitted if it 'rests on a reliable foundation and is relevant.'" *Tyree v. Boston Scientific Corp.*, 54 F.Supp.3d 501, 516 (S.D. W. Va. 2014) (quoting *Daubert*, 509 U.S. at 597). Although "[t]he proponent of expert testimony does not have the burden to 'prove' anything to the court," he or she must nonetheless "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.* (quoting *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998)).

The Supreme Court has provided a non-exhaustive list of factors for a judge to consider in applying F.R.E. 702: "(1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999); *Daubert*, 509 U.S. at 592-94). "The inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir.1999) (quoting *Daubert*, 509 U.S. at 594-95). Even so, "'[e]xpert witnesses have the potential to be both powerful and quite misleading[;]' the [trial] court must 'ensure that any and all scientific testimony . . . is not only relevant, but reliable.'" *Tyree*, 54 F.Supp.3d at 516 (quoting *Cooper*, 259 F.3d at 199).

ARGUMENT

A. Dr. Serels Is Not Qualified to Offer Opinions on Degradation, Cytotoxicity, or Mesh Design Generally, Including the Significance of Laser-Cut Versus Mechanically Cut Mesh.

Here, as stated, Dr. Serels opines that "[t]he TVT's design and material is reasonably safe for its intended use," and more specifically that mesh does not degrade or undergo particle loss, that there is no clinical difference between mechanical and laser-cut mesh, and that claims of cytotoxicity "are not accompanied by any methodologically sound or scientific analysis, and is [*sic*] completely lacking in clinical significance." Ex. C, §§ I.9; III. These matters are far beyond Dr. Serels's expertise, knowledge, and experience.

For example, on the issue of degradation and particle loss, Dr. Serels admits that he not an expert in chemical engineering, surgical pathology, polymer chemistry, or biomaterials. Ex. B, 28:10-29:10. He further admits that he has not performed bench testing research or any kind of lab research on polypropylene mesh. *Id.* at 28:23-29:4. He has not performed any type of pathological analysis on polypropylene mesh, and he has never studied polypropylene under a microscope to determine degradation. *Id.* at 29:5-29:18. Similarly, he has never studied a chemical analysis of polypropylene to determine degradation. *Id.* at 29:20-30:1. He has never published any findings showing that polypropylene does not degrade in the human body. *Id.* at 29:11-14. Further, he is not an expert on raw materials, and he does not know whether raw materials "would make a difference in the clinical effects of the sling." *Id.* at 162:20-163:14. He has done no kind of study on that issue. *Id.* at 163:17-21.

As such, Dr. Serels has not "come forward with evidence from which the court can determine" that he is qualified to testify regarding degradation and particle loss. *Tyree, supra*. The same is true of his unsupported statement regarding cytotoxicity. In addition to the lack of relevant

qualifications noted above, Dr. Serels does not know what ISO testing is, and he is not familiar with ISO standards. Ex. B, 34:21-23; *cf.* Ex. F (Elliott Report), at 27-30 (describing TVT cytotoxicity and ISO testing with citation to Ethicon documents, deposition testimony, and scientific literature).

As far as design, Dr. Serels testified that he does not know what a design and failure modes effects analysis is, he does not know what a process failure modes effects analysis is, and he does not know what an application failure modes effect analysis is. Ex. B, 33:4-34:15. Dr. Serels has never reviewed the design history of the TVT. *Id.* at 34:16-19. He has never reviewed Ethicon's internal standard operating procedures relating to medical device design. *Id.* at 34:24-35:5. He does not know the standards or operating procedures for designing mesh products. *Id.* at 32:16-21. He does not know the responsibilities of a manufacturer as far as designing mesh products. *Id.* at 32:23-33:4. He holds no design patents. *Id.* at 35:21-23. He does not know the pore size of Prolene mesh. *Id.* at 50:22-24. He does not know the weight of the TVT mesh. *Id.* at 52:10-12. He has no idea why Prolene mesh was originally developed or what it is used for. *Id.* at 52:13-16. Dr. Serels is "not familiar with the differences" between the Prolene mesh used in the TVT and mesh used in other devices. *Id.* at 136:8-137:2. He assumes "they're similar enough." *Id.* at 162:20-163:3.

When asked about the difference between laser-cut and mechanically cut mesh, Dr. Serels offered this unhelpful observation:

> Q Doctor, do you know the difference between a laser cut and mechanical cut TVT product?
>
> A To some extent, yes.
>
> Q Explain that for me. What do you mean by to some extent?
>
> A Well, I'm not an expert on making mesh materials, but I think as it applies, if you cut a piece of mesh with a laser, it's known as laser cut, and if you cut a piece of

> mesh with some kind of a different cutting device, more of a mechanic device, it's a mechanical cut material.

Id. at 103:14-24.

Dr. Serels also admitted that he has no idea how to identify whether a particular mesh product is laser-cut or mechanically cut. *Id.* at 104:1-4 ("No. Unless I was told, I wouldn't know."). In his practice, he does not know whether particular devices are laser-cut, and it is of "no consequence" to him. *Id.* at 104:5-105:8. He has not kept track of the number of patients receiving laser-cut devices, nor has he tracked the relative complication rates between patients receiving laser-cut implants and those receiving mechanically cut products. *Id.* at 104:5-8; 105:9-19. He "ha[s] no idea" when laser-cut mesh was first used in TVT. *Id.* at 108:3-4. He "[p]robably" became aware of the existence of laser-cut mesh in 2006. *Id.* at 108:6-13. He is unfamiliar with the purported advantages of laser-cut mesh, and he does not know why Ethicon introduced it. *Id.* at 108:14-109:6. He is also not aware of any studies comparing mechanically cut devices versus laser-cut devices. *Id.* at 161:3-8. He has not tracked or looked at complaint analysis or trends for mechanically cut mesh versus laser-cut products. *Id.* at 105:16-19. He also acknowledged that he did not recall reviewing the clinical expert report for laser-cut mesh. *Id.* at 36:14-37:7.

Again, then, Dr. Serels has not "come forward with evidence from which the court can determine" that he is qualified to testify regarding mesh design and the significance of laser-cut versus mechanically cut mesh. His opinions should be excluded accordingly.

B. <u>Dr. Serels Offers No Reliable Basis for His Opinions on Degradation, Cytotoxicity, or Mesh Design Generally, Including the Significance of Laser-Cut Versus Mechanically Cut Mesh.</u>

Aside from failing to offer the Court a basis for finding him qualified to testify on these matters, Dr. Serels also fails to provide a reliable basis for his opinions. Indeed, Dr. Serels does

not show that he utilized any method—let alone a scientifically reliable method—for arriving at his opinions.

Often, Dr. Serels simply states his opinion as a conclusion with no supporting information. *E.g.*, Ex. C, § III ("These claims are not accompanied by any methodologically sound or scientific analysis, and is [*sic*] completely lacking in clinical significance."). Other times, the basis for his conclusions are either irrelevant, because they do not fit the case, or directly undermined by his own deposition testimony. For example, Dr. Serels writes in his report that degradation and cytotoxicity are unproven in pelvic mesh applications, because "[p]olypropylene has been used as a surgical suture for approximately 40 years and as a surgical hernia mesh for approximately 30 years," and "[t]hese concerns have not proven true with these uses." *Id*. Further, in his deposition, Dr. Serels was asked if he knew "whether or not the TVT mesh is manufactured from the same material as the Prolene suture," and responded, "I have no idea…. I know it's polypropylene…. I don't know the details. I don't manufacture mesh. I don't know. I don't know the subtleties in how to manufacture mesh." Ex. B, at 142:13-21. He does not know whether raw materials "would make a difference in the clinical effects of the sling." *Id.* at 162:20-163:14. In other words, Dr. Serles does not offer a scientifically reliable method for determining that the TVT does not undergo degradation and particle loss in the pelvic floor.

Likewise, in his report, he claims that "Ethicon still sells both mechanically cut and laser cut TVT in order to satisfy surgeon preferences," and then asserts without citation that "[t]here has been rigorous clinical data from implants prepared using the 2 different techniques," with "robust opportunity to assess for any difference in outcomes," but "[n]one have been observed." Ex. C, § III. However, when questioned about this in his deposition, Dr. Serels testified that he is unfamiliar with the alleged advantage of laser-cut mesh, or why Ethicon introduced it. *Id.* at 108:14-109:6.

He is also not aware of any studies comparing mechanically cut devices versus laser-cut devices. *Id.* at 161:3-8. He has not tracked or looked at complaint analysis or trends for mechanically cut mesh versus laser-cut products. *Id.* at 105:16-19. And he also acknowledged that he did not recall reviewing the clinical expert report for laser-cut mesh. *Id.* at 36:14-37:7. Clearly, then, he has offered no reliable basis for his opinions on mesh cutting techniques and whether there are clinically significant differences.

Elsewhere, the most Dr. Serels can muster is *ipse dixit*. He repeatedly states in his report that he has not "experienced" or "seen" certain properties of mesh. *E.g.*, Ex. C, § III ("Such claims are not supported by any level 1 evidence, nor have I experienced any complications attributable to alleged particle loss or degradation in my 20 years of clinical practice."); *id.* ("In addition, I have not seen any level I scientific study to prove that polypropylene used vaginally will results in any of the above occurrence. Furthermore, over the last 20 years of clinical practice I have not seen any evidence of [*sic*] to support these findings."). This is not a proper basis for expert testimony. *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 701 (S.D. W. Va. 2014) ("[E]xperience without reliable, testable methodology is not sufficient.") (quoting *Brown v. Burlington N. Santa Fe Ry. Co.*, 765 F.3d 765, 776 (7th Cir. 2014)) (alteration in original). Of course, it is not surprising that Dr. Serels does not recall ever reviewing any conflicting information, given his admission that he spent less than two hours reviewing deposition testimony, other expert reports, internal Ethicon documents, and scientific literature. Ex. B, 8:11-21; 21:21-22:3. Indeed, it is evident that Dr. Serels's common refrain that he is unaware of any literature contrary to his own opinion is due to his willing failure to review certain evidence:

> Q Doctor, is it your testimony that you've reviewed the dozens of Ethicon corporate deposition employees cited in Dr. Rosenzweig's, Elliot's, and Blaivas's reports in one to two hours?

A No.

Q Have you reviewed those reports?

A I've stated that I reviewed Dr. Blaivas's report. I did not state I reviewed dozens of other employee depositions.

Q Well, it also states that you reviewed the materials cited in Dr. Blaivas's report, is that true or not true?

A I reviewed his report, but not necessarily each and every reference that he listed.
Q Is there a listing of the references he cited that you did review somewhere that could be made available?

A Not that I know of.

Q So you would agree with me that you haven't reviewed all the materials cited in Dr. Blaivas's expert report, correct?

A No, I have not looked at each and every reference that he cited individually, no.

Q And you would agree with me that you haven't reviewed all the materials cited in Dr. Elliot's expert report?

A In a similar way, yes, you're correct.

Q And you would agree with me that you haven't reviewed all the materials cited in Dr. Rosenzweig's expert report?

A Correct.

….

A My opinion is that I'm an expert in this area, and I can give an opinion on this topic of discussion even if I haven't read every word of someone else's opinion.

Q Would you agree that there could be information out there either in published literature or in the form of internal documents that you haven't seen that could change your opinion in this case?

A I suppose anything is possible, but I think my expert opinion is pretty unwavering based on my expertise.

Ex. B, 115:9-118:22.

Thus, Dr. Serels did not—and according to him, need not have—reviewed contrary scientific evidence, because his opinions are "pretty unwavering" based on his personal experience. However, had Dr. Serels reviewed the materials cited in the Blaivas, Elliott, and Rosenzweig reports, he would have been confronted with evidence tending to refute his theories. *See, e.g,* Ex. G (Blaivas Report), at ¶¶ 44-50 (describing the significance of laser-cut versus mechanically cut mesh and the risks unique to each, with citation to Ethicon documents and deposition and trial testimony); Ex. F (Elliott Report), at 27-30 (describing mesh cytotoxicity with citation to Ethicon documents, deposition testimony, and scientific literature); Ex. H (Rosenzweig Report), at 14-22 (describing mesh degradation with citation to Ethicon documents, deposition testimony, and scientific literature).[1]

As this Court has observed, "[a]n expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.'" *Tyree*, 54 F.Supp.3d at 520: (quoting *In re Rezulin Products Liab. Litig.*, 369 F.Supp.2d 398, 425 (S.D.N.Y. 2005) (quotations omitted)). Where, as here, the "relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.'" *Id.*

For the stated reasons, Dr. Serels's opinions on mesh degradation and particle loss, mesh cytotoxicity, and mesh design, including the differences between laser-cut and mechanically cut mesh, should be excluded.

[1] Dr. Rosenzweig has adopted this prior report for purposes of this litigation. *See* Case No. 2:12-md-02327, Doc. 1815.

C. Dr. Serels Is Not Qualified to Speak to the Adequacy of the TVT IFU.

Here, as stated, Dr. Serels offers the opinion that "[t]he Instructions for Use adequately and appropriately warns physicians trained in the surgical treatment of stress urinary incontinence of the potential adverse reactions associated with the device." Ex. C, § I.9. Dr. Serels is not qualified to offer this opinion.

He admits that he is not an expert on medical device warnings. *Id.* at 30:3-8. He does not know the standards that govern risk information or any relevant guidelines. *Id.* at 30:10-16. In fact, he agreed he has no understanding of any standard whatsoever as to what risks and complications are supposed to be disclosed in an IFU. *Id.* at 123:6-10. He does not know what department is involved in creating warnings for a medical device. *Id.* at 30:17-21. He has never drafted or been involved in drafting warnings, precautions, or adverse reactions for a medical device. *Id.* at 31:9-13. He has never studied the question of what information should be included in a pelvic mesh IFU. *Id.* at 128:2-5. He is not familiar with the differences between various Ethicon IFUs. *Id.* at 147:22-148:4. As such, he has not offered this Court sufficient proof that the adequacy of IFUs is within his area of expertise; those opinions should be excluded.

D. Dr. Serels Has No Reliable Basis for His Opinions Regarding the TVT IFU.

Additionally, Dr. Serels has no reliable basis for offering opinions regarding the adequacy of Ethicon's TVT IFU. Although it is not immediately clear from his report, the basis for his opinions regarding the IFU are evidently *not* that the TVT IFU sufficiently warned of all risks—but that in his personal experience the issue is irrelevant because doctors do not rely on the IFU. *E.g.,* Ex. B, 119:6-9 ("I think as a physician what's written in the IFU is not necessarily as important as what one's peers do and what's published in the literature."); 120:3-6 ("[M]y opinion

still stands that the IFU isn't really what's relied upon by physicians to look for adverse events. Most physicians probably don't even read the IFUs."). Indeed, on the merits of adequacy, Dr. Serels admits that many items omitted from the pre-2015 IFU should have been included. *Id. at* 128:24-131:23 ("I think it's reasonable to have those in there. I just stated before I don't think physicians rely on the IFU."). He does not know when or if those adverse events were actually included. *Id.* at 131:9-11. He was not aware that the TVT IFU was updated last year, although he agrees "it would be important prior to offering an opinion on [IFUs] to know that there was a significant update to the TVT IFU." *Id.* at 118:23-120:6. If Dr. Serels does not know the contents of the IFU, he cannot reliably state that the IFU is adequate.

As far as his opinion that doctors do not rely on IFUs, Dr. Serels writes in his report that "[i]t is well known by all pelvic floor surgeons that any surgery for stress urinary incontinence or pelvic organ prolapse, with or without the use of mesh, can potentially cause complications that can be temporary or permanent, including but not limited to: pelvic pain, dyspareunia (pain with sexual intercourse), scarring, vaginal narrowing, leg/groin pain, urinary retention and other voiding problems." Ex. C, § III. Dr. Serels does not offer support for the contention that "all pelvic floor surgeons" have such knowledge, and his deposition testimony suggests that this conclusion is based only on his personal experience as a surgeon, although he admits that his experience may not be the same as every other doctor's. Ex. B, 120:3-121:4; 123:20-124:5. He has made no effort to confirm that his understanding of what needs to be in an IFU is consistent with that of other surgeons. *Id.* at 6-11. And he has no "objective standard" for determining what should or should not be included in an IFU:

> Q Doctor, as you sit here today, do you have any understanding of any standard whatsoever as to what risks and complications are supposed to be disclosed in an IFU?

A No.

Q So you're not relying on any objective standard from any source?

A Correct.

Q Have you made any effort before today to find out what FDA regulations require a medical device company to disclose in an IFU?

A No.

Id. at 123:6-13.

Similarly, he writes that roping and curling of the mesh result from too much applied tension, "which is clearly contrary to what is outlined in the surgical steps of the IFU." Ex. C, § III. He further states that an occurrence of curling "is only possible" in this manner. *Id.* Dr. Serels has no reliable basis for these statements, as revealed in his deposition. He concedes that he does not know the extent to which the TVT IFU describes tensioning at all. Ex. B, 147:18-21 ("I think it's – there are vague suggestions on how to tension a sling of any sort."). He does not know whether the IFU directs placement with "minimal tension." *Id.* at 148:13-18. "I'm not familiar with those IFUs to the extent that I remember seeing either of those terms [relating to tension]," he says. *Id.* at 148:20-149:1. He further stated that he's "not sure" whether the TVT IFU directs a physician to place the sling without tension: "certainly it's been described as a tension free device, but that's always been somewhat of a misnomer amongst surgeons." *Id.* at 148:5-11.

Again, it turns out that Dr. Serels's opinion is *not* that the IFU (or any other Ethicon training) sufficiently explains the way to properly tension the device, but rather that it is irrelevant, because the responsibility fall on the surgeon:

Q Do you have an opinion in this case regarding whether or not Ethicon does or does not properly instruct physicians on how to tension the TVT device?

A My opinion is that I don't think it's the device company's responsibility to teach someone how to tension the sling….

> …I think as a surgeon, you need to realize how best to use a product in your own hands based on your experience and the experience of your peers, and I really don't think many people rely upon an IFU to make that determination. I certainly don't.

Id. at 147:6-12; 149:8-12.

In sum, Dr. Serels has not shown that he is qualified to discuss the adequacy of medical device instructions. Beyond that, he has no reliable basis for testifying about the TVT IFU, because he plainly acknowledges that he has no idea of the contents; instead, he finds the IFU discussion irrelevant, because he does not—and therefore all surgeons do not—rely on the IFU. These opinions fail the measures of Rule 702 and *Daubert* set out above and should be excluded.

E. Dr. Serels Has No Reliable Basis for His Opinions Regarding Alternative Treatments for SUI.

Dr. Serels writes in his report that certain "complications occur in all procedures for stress incontinence and are not unique to mid-urethral slings," and that "the TVT appears safer than either the Burch procedure or pubovaginal sling." Ex. C, § III.

Dr. Serels provides no explanation for these conclusions, and they should be excluded as lacking a discernible basis for admissiblity. *Tyree, supra*. It is unclear what he means when he says the TVT "appears safer," but presumably it is based on his personal experience. *See* Ex. B, 27:11-28:1 (discussing his use of Burch and biologic slings). As such, it should be excluded. *Eghnayem, supra*.

Further, had Dr. Serels reviewed the materials he claimed to have reviewed, he would have been confronted with scientific literature refuting his position. *E.g.*, Ex. G (Blaivas Report), at ¶¶ 19-23 (describing the risks unique to mesh slings and comparing mesh implantation to alternative surgical procedures). He has offered no response to those findings and his testimony should be excluded accordingly. *Tyree, supra*.

F. Certain of Dr. Serels's Opinions Constitute Legal Conclusions.

This Court has repeatedly held that "'opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.'" *Tyree*, 54 F.Supp.3d at 518 (quoting *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)). Nonetheless, Dr. Serels usurps the fact-finder's function in several instances. *See, e.g.*, Ex. C, § I.9 ("the TVT's design and material is reasonably safe for its intended use and the Instructions for Use adequately and appropriately warns physicians"); § III ("I have an intimate understanding of what the reasonably prudent pelvic floor surgeon should know…."). These statements are improper and should be excluded.

G. Certain of Dr. Serels's Opinions Are Irrelevant and Inflammatory.

Finally, Dr. Serels concludes his written report with the following:

> It has also become quite popular to blame one's incontinence procedure for many ailments that are unrelated. It is also the legal system and the allure of compensation that can sometimes bring out the worst in people. It is this type of temptation that destroys the evolutionary advancements in the treatment of stress urinary incontinence. Without the continued use of the polypropylene mesh sling, it would set back the treatment of female SUI by at least two decades.

Ex. C, § III ; *see also id.* at § II.I.2 ("All of the controversy with polypropylene slings started with the FDA and its review of polypropylene mesh use for vaginal vault prolapse….. The sling was investigated only because it was made out of a similar material…. It is my contention that polypropylene mesh slings are a wonderful advancement that needs [*sic*] to be integral [*sic*] part of our treatment.").

All of this is immaterial and prejudicial grandstanding. It has no place in the courtroom, and certainly not in the form of "expert" testimony. It should be excluded pursuant to Federal Rules of Evidence 401, 402, and 403.

CONCLUSION

For these reasons, Plaintiffs ask that this Court grant their motion and exclude or otherwise limit the opinions and testimony of Dr. Serels.

Dated: April 27, 2016

Respectfully submitted,
Wave 1 Plaintiffs

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of April, 2016, I electronically filed the foregoing document with the Clerk of the court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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